

**COPPERTONE WATERBABIES WHIPPED SPF 50- avobenzone, homosalate, octisalate, octocrylene lotion**

**Bayer HealthCare LLC.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Coppertone Waterbabies Whipped SPF 50 UI 1614117**

***Drug Facts***

***Active ingredients***

(To Deliver) Avobenzone 3%, Homosalate 9%, Octisalate 4.5%,  
Octocrylene 9%

***Purpose***

Sunscreen

**Uses**

***Uses***

- helps prevent sunburn
- if used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun

***Warnings***

**For external use only**

**Do not use** on damaged or broken skin

**When using this product**

- keep out of eyes. Rinse with water to remove.
- use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.
- do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

**Stop use and ask a doctor if** rash occurs

**Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

***Directions***

- apply liberally 15 minutes before sun exposure ■ do not dispense or apply directly on face. Dispense into hands and apply to face ■ use in well-ventilated areas ■ reapply: ■ after 80 minutes of swimming or sweating ■ immediately after towel drying ■ at least every 2 hours ■ **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: ■ limit time in the sun, especially from 10 a.m.– 2 p.m. ■ wear long-sleeve shirts, pants, hats, and sunglasses ■ children under 6 months: Ask a doctor

## **Other information**

### ***Other information***

- protect this product from excessive heat and direct sun
- avoid long term storage above 40°C (104°F)
- may stain or damage some fabrics or surfaces

***Inactive ingredients*** water, aluminum starch octenylsuccinate, styrene/acrylates copolymer, behenyl alcohol, glycerin, dicaprylyl ether, nitrous oxide, microcrystalline cellulose, glyceryl stearate, cetyl alcohol, sodium ascorbyl phosphate, tocopherol, lecithin, palmitic acid, stearic acid, myristyl alcohol, lauryl alcohol, caprylyl glycol, cellulose gum, hydroxyacetophenone, 1,2-hexanediol, butylated PVP, disodium EDTA

***Questions?*** 1-866-288-3330

## **Package label display**

Coppertone®  
SUNSCREEN  
water babies®  
Whipped

Soft & Gentle 50

Fast Absorbing

#1 Pediatrician

Recommended brand

No Dyes, PABA, Oxybenzone

Water Resistant (80 Minutes)

Broad Spectrum SPF 50

NET WT 5 OZ (142 g)

|   |  |  |  |                   |  |   |                             |   |  |  |  |   |  |  |  |   |  |
|---|--|--|--|-------------------|--|---|-----------------------------|---|--|--|--|---|--|--|--|---|--|
|  <p><b>Coppertone</b><br/>SUNSCREEN<sup>®</sup></p> <p><b>water babies</b><sup>®</sup></p> <p>Whipped</p> <p>Soft &amp; Gentle<br/>Fast Absorbing</p> <p><b>50</b></p> <p>#1 Pediatrician Recommended brand</p> <p>No Dyes, PABA, Oxybenzone</p> <p>Water Resistant (80 Minutes)<br/>Broad Spectrum SPF 50</p> <p>NET WT 5 OZ (142 g)</p>  |  | <p><b>Coppertone WaterBabies<sup>®</sup> Whipped Sunscreen</b> provides UVA/UVB protection in a soft and gentle form that spreads easily on baby's delicate skin. The gentle formula is dermatologist-tested and free of fragrances, dyes, oils, PABA, Oxybenzone.</p> <table border="1"> <tr> <td colspan="2"><b>Drug Facts</b></td> </tr> <tr> <td><b>Active ingredients</b><br/>(To Deliver) Avobenzone 3%, Homosalate 9%, Octisalate 4.5%, Octocrylene 9%</td> <td><b>Purpose</b><br/>Sunscreen</td> </tr> <tr> <td colspan="2"><b>Uses</b><br/>■ helps prevent sunburn<br/>■ if used as directed with other sun protection measures (see <b>Directions</b>), decreases the risk of skin cancer and early skin aging caused by the sun</td> </tr> <tr> <td colspan="2"><b>Warnings</b><br/><b>For external use only</b><br/><b>Do not use</b> on damaged or broken skin<br/><b>When using this product</b><br/>■ keep out of eyes. Rinse with water to remove.<br/>■ use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.<br/>■ do not puncture or incinerate. Contents under pressure. 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## COPPERTONE WATERBABIES WHIPPED SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

|                         |                |                    |                |
|-------------------------|----------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:11523-7453 |
| Route of Administration | TOPICAL        |                    |                |

Active Ingredient/Active Moiety

| Ingredient Name  |                                   | Basis of Strength                                 | Strength             |                    |
|--|-----------------------------------|---|----------------------|--------------------|
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)       |                                   | AVOBENZONE  | 30 mg in 1 g         |                    |
| OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)   |                                   | OCTISALATE  | 45 mg in 1 g         |                    |
| OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM) |                                   | OCTOCRYLENE                                       | 90 mg in 1 g         |                    |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)       |                                   | HOMOSALATE  | 90 mg in 1 g         |                    |
|  |                                   |   |                      |                    |
| Inactive Ingredients   |                                   |   |                      |                    |
| Ingredient Name  |                                   |   | Strength             |                    |
| DICAPRYLYL ETHER (UNII: 77JZM5516Z)                                |                                   |   |                      |                    |
| NITROUS OXIDE (UNII: K50XQU1029)                                   |                                   |   |                      |                    |
| MYRISTYL ALCOHOL (UNII: V42034O9PU)                                |                                   |   |                      |                    |
| CETYL ALCOHOL (UNII: 936JST6JCN)                                   |                                   |   |                      |                    |
| GLYCERIN (UNII: PDC6A3C0OX)  |                                   |   |                      |                    |
| HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)                             |                                   |   |                      |                    |
| WATER (UNII: 059QF0KO0R)   |                                   |   |                      |                    |
| ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)                |                                   |   |                      |                    |
| SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)                       |                                   |   |                      |                    |
| PALMITIC ACID (UNII: 2V16EO95HI)                                   |                                   |   |                      |                    |
| 1,2-HEXANEDIOL (UNII: TR046Y3K1G)                                  |                                   |   |                      |                    |
| TOCOPHEROL (UNII: R0ZB2556P8)                                      |                                   |   |                      |                    |
| LAURYL ALCOHOL (UNII: 178A96NLP2)                                  |                                   |   |                      |                    |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                                 |                                   |   |                      |                    |
| STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)        |                                   |   |                      |                    |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62)                               |                                   |   |                      |                    |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)                      |                                   |   |                      |                    |
| EDETATE DISODIUM (UNII: 7FLD91C86K)                                |                                   |   |                      |                    |
|  |                                   |   |                      |                    |
| Product Characteristics  |                                   |   |                      |                    |
| Color  | white (off white to light yellow) | Score   |                      |                    |
| Shape  |                                   | Size  |                      |                    |
| Flavor   |                                   | Imprint Code                                      |                      |                    |
| Contains   |                                   |   |                      |                    |
|  |                                   |   |                      |                    |
| Packaging  |                                   |   |                      |                    |
| #  | Item Code                         | Package Description                               | Marketing Start Date | Marketing End Date |
| 1  | NDC:11523-7453-1                  | 142 g in 1 CAN; Type 0: Not a Combination Product | 11/01/2018           | 09/01/2021         |
|  |                                   |   |                      |                    |
| Marketing Information  |                                   |   |                      |                    |
| Marketing Category   |                                   | Application Number or Monograph Citation          | Marketing Start Date | Marketing End Date |
| OTC monograph not final  |                                   | part352   | 11/01/2018           | 09/01/2021         |

